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| APPLICATION NO.                     | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.        |  |
|-------------------------------------|-----------------|----------------------|-------------------------|-------------------------|--|
| 10/828,972                          | 04/21/2004      | Rex A. Niles         | 223P164                 | 5414                    |  |
| 408                                 | 7590 09/29/2005 |                      | EXAMINER                |                         |  |
| LUEDEKA, NEELY & GRAHAM, P.C.       |                 |                      | PATEL, MITAL B          |                         |  |
| P O BOX 1871<br>KNOXVILLE, TN 37901 |                 |                      | ART UNIT                | PAPER NUMBER            |  |
|                                     |                 |                      | 3743                    |                         |  |
|                                     |                 |                      | DATE MAILED: 09/29/2003 | DATE MAILED: 09/29/2005 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)  |
|---|--|---|
|   | 10/828,972   | NILES ET AL.  |
| Office Action Summary   | Examiner   | Art Unit  |
|   | Mital B. Patel   | 3743  |
| The MAILING DATE of this communication app<br>Period for Reply  | pears on the cover sheet with the c  | orrespondence address   |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period or Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N.  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133). |
| Status  |  |   |
| <ol> <li>Responsive to communication(s) filed on 11 Jets</li> <li>This action is FINAL.</li> <li>Since this application is in condition for allowated closed in accordance with the practice under Exercise.</li> </ol>   | action is non-final.  nce except for formal matters, pro   |   |
| Disposition of Claims   |  |   |
| 4) ☐ Claim(s) 1-10 is/are pending in the application 4a) Of the above claim(s) 10 is/are withdrawn for the state of the above claim(s) 10 is/are withdrawn for the state of t | from consideration.  |   |
| Application Papers  | ·  |   |
| 9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 11 July 2005 is/are: a)  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Example 11.  | ☑ accepted or b) ☐ objected to be drawing(s) be held in abeyance. Settion is required if the drawing(s) is object.   | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).                          |
| Priority under 35 U.S.C. § 119  |  |   |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burea * See the attached detailed Office action for a list  | ts have been received.<br>ts have been received in Applicati<br>onty documents have been receive<br>u (PCT Rule 17.2(a)).  | on No ed in this National Stage   |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail D  5) Notice of Informal F  6) Other:  |   |

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#### **DETAILED ACTION**

## Response to Amendment/Arguments

- 1. Applicant's arguments filed 7/11/05 have been fully considered but they are not persuasive.
- 2. In response to Applicant's arguments that Briggs III does not teach an auxiliary gas inlet port that extends into the first chamber at a position removed from the interior of the nebulizing chamber, it should be noted that the auxiliary port of Briggs is removed from the interior of the nebulizing chamber (See Fig. 1). Furthermore, "at a position removed from the interior" is vague and/or relative since Applicant has not disclosed what "at a position removed from the interior" is limited to with respect to the other structural elements.
- 3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the supplemental gas is introduced into the first chamber *only*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- 4. In response to Applicant's arguments regarding dependent claims 5 and 6, the Examiner directs Applicant's attention to Figure 1 of Briggs III, which shows the recited limitations.

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## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Briggs, III (US 6,041,776).
- As to claim 1, Briggs, III teaches a nebulizer head 12,12a (See Figs. 1 and 2) 7. having an auxiliary gas inlet port 52, 52a for introducing a supplemental gas, comprising: a first chamber (See Figs. 1-2) having a closed top, enclosing sides and an open bottom adapted to receive for coupling thereto a receptacle 14,14a adapted to contain a liquid medicant 42.42a to be dispensed at a predetermined rate of concentration; a second nebulizing chamber 26,26a carried within said first chamber at a position spaced from said closed top and extending downwardly therefrom; said nebulizing chamber having an open bottom adapted to pass outwardly therethrough entrained and nebulized liquid medicant; a nebulizing nozzle 36,36a in fluid communication with said nebulizing chamber for creating a nebulized aerosol from liquid medicant coupled thereto; means 38,38a for coupling a flow of nebulizing gas into said first chamber to said nebulizing nozzle and through said second nebulizing chamber carried within said first chamber; an aspirator tube 40,40a having a first end positioned in fluid communication adjacent to said nebulizing nozzle, and a second end positioned to be received into liquid medicant contained within the receptacle; an auxiliary gas inlet

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**52,52a** port for introducing a supplemental gas into said first chamber extending into said first chamber at a position removed from the interior of said nebulizing chamber; and said first chamber having a discharge outlet **50** spaced from said open bottom of said nebulizing chamber and said auxiliary gas inlet port for discharging liquid medicant entrained in said nebulizing chamber and the supplemental gas introduced into said first chamber through said auxiliary gas inlet port.

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- 8. **As to claim 2**, Briggs, III teaches a nebulizer head wherein said auxiliary gas inlet port and said discharge outlet are in opposed positions relative to each other, and said nebulizing chamber carried within said first chamber extends therebetween (**See Figs. 1 and 2**).
- 9. **As to claim 3**, Briggs, III teaches a nebulizer head further including a receptacle **14.14a** for containing liquid medicant to be dispensed through said discharge outlet.
- 10. **As to claim 4**, Briggs, III teaches a nebulizer head wherein said receptacle includes means **46,46a** for releasibly connecting said receptacle to said first chamber in sealing engagement therewith.
- 11. **As to claim 5**, Briggs, III teaches a nebulizer head wherein said nebulizing chamber has an open top attached to the interior of said first chamber at a position above said auxiliary gas inlet port and said nebulizing chamber extends downwardly therefrom such that said open bottom of said nebulizing chamber is positioned at a location removed from said auxiliary gas inlet port (**See Figs. 1-2**).
- 12. As to claim 6, Briggs, III teaches a nebulizer head wherein said nebulizing nozzle is supported from said first chamber top above said nebulizing chamber for

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entraining liquid medicant communicated thereto through said aspirator tube (See Figs. 1-2).

- 13. **As to claim 7**, Briggs, III teaches a nebulizer head wherein said nebulizing chamber extends downwardly within said first chamber such that said open bottom of said nebulizing chamber is positioned at a location below said auxiliary gas inlet port and below said first chamber discharge outlet (**See Figs. 1-2**).
- 14. **As to claim 8**, Briggs, III teaches a nebulizer head wherein said means for coupling a flow of nebulizing gas into said first chamber comprises an adapter **38,38a** for releasably coupling a source of driving gas to said nebulizing nozzle.
- 15. **As to claim 9**, Briggs, III teaches a nebulizer head wherein said auxiliary gas inlet port includes means **56** for selectively closing said auxiliary gas inlet port when not in use.

#### Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel Primary Examiner Art Unit 3743